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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,194	06/22/2001	Anthony J. Kinney	BB1449 US NA	9205

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EXAMINER
ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,194	KINNEY ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

1. New claims 53-59 are pending and under examination in this application. Claims 1-45 were cancelled by Applicant in the communication filed 10/29/2004. Claims 46-52 were cancelled by Applicant in the communication filed 10/21/2005.

Applicant's response filed 10/21/2005 has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed 04/21/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 53-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terminology "unrelated to any endogenous RNA in the host" in claims 53 and 54 and "unrelated to any endogenous RNA in soybean" in claims 57 and 58 is a relative term which renders the claim indefinite. The term "unrelated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, the metes and bounds

of what degree of unrelated would be required to meet this claim limitation cannot be determined, without assumption.

3. Claims 53-55 and 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 53, 55 and 57 each, "and are in proximity to a sequence homologous to all or part of the RNA in (a)...". Claims 54 and 58 recite the phrases, "and is located 3' to a sequence homologous to all or part of the RNA in (a)...". and "and is located 3' to a sequence homologous to all or part of the RNA in (a)...". There is insufficient antecedent basis for this limitation in the instant claims because (a) in each claim recites, "homology to at least one target mRNA expressed in soybean...". A reference is made to RNA in the previous line but there is no RNA recited in (a) and no assumption can be made as to what is being distinctly claimed with by "the RNA in (a).

4. Claims 53, 55 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the instant claims recites, "and are in proximity to a sequence homologous to all or part of the RNA in (a)...". The terminology is relative terminology which renders the claim indefinite. The terminology is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the

scope of the invention. In particular, the metes and bounds of what it means to be "in proximity to" a nucleotide sequence, cannot be determined, without assumption.

5. Claims 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 53 and 54 recite the limitation "the host" in lines 6 and lines 5-6 respectively. There is insufficient antecedent basis for this limitation in the claim. In particular, the claims are limited only to a recombinant construct comprising a promoter operably linked to a DNA sequence and recite the intended use "when expressed in soybean." The claims to the construct, however, are not limited to a construct that can only be expressed in soybean, for example. Therefore, "the host" could be any host and the metes and bounds of what is being claimed cannot be determined by the skilled artisan, without assumption.

6. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 54 recites, "comprising at least nucleotides 7-36 or 7-36 and 44-73 and is located ..." in lines 6-7 and "comprising at least nucleotides 82-111 or 82-111 and 119-148" in line 9-10. The skilled artisan cannot determine the metes and bounds of what is being claimed with this number range, without assumption.

7. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 55 is drawn to a promoter linked to a DNA sequence and recites that "said DNA sequence is introduced into the Not 1 site of SEQ ID NO: 13." The claim as written, however, cannot be reasonably interpreted because it appears to be drawn to a DNA sequence that, when expressed, produces an RNA transcript of SEQ ID NO: 13 that comprises a Not1 site as set forth in (b) wherein that DNA sequence, set forth as "said sequence" in line 9, is introduced into the Not1 site of itself. The skilled artisan cannot determine the metes and bounds of what is being claimed with this language without assumption because it is extremely confusing and unclear.

8. Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 56 is drawn to a method comprising transforming soybean with any of the recombinant constructs of claims 46-47. However, claims 46-47 have been cancelled in the instant Application. Therefore, the skilled artisan cannot determine the metes and bounds of what is being claimed, without assumption, because there is lack of antecedent basis for the terminology, "claims 46-47."

9. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 58 recites, "comprising at least nucleotides 7-36 or 7-36 and 44-73 and is located ..." in line 5 and "comprising at least nucleotides 82-111 or 82-111 and 119-148" in lines 7-8. The skilled artisan cannot determine the metes and bounds of what is being claimed with this number range, without assumption.

10. Claims 53-54, 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 53-54, 57 and 58 recite specific portions of SEQ ID NO: 13 (Claims 46-47 and 49-52 which are new limitations to the claims introduced by amendment in the communication filed 10/29/04. Applicant has indicated, in the remarks filed 10/29/04, where support for the newly added limitations of particular regions of SEQ ID NO: 13 can be found in the specification (pg. 18, lines 12-34 and pg. 2, lines 34-36). However, no support for the newly added limitations of particular regions of SEQ ID NO: 13 could be located in the specification and claims as originally filed, including the particular parts of the specification pointed to by Applicant. If Applicant believes that particular support for the newly added limitations of particular regions of SEQ ID NO: 13 is to be found in the specification or claims as originally filed, Applicant should point, with particularity, to where such support may be found.

11. Claims 53-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 53-59 are broadly drawn to compositions and methods comprising a vast genera of recombinant constructs and the RNA's that are expressed from such that reduce the expression of target mRNAs or any endogenous mRNAs expressed in soybean that have at least 80% sequence identity with a sequence homologous to all or part of the target mRNA. However, the specification as filed does not provide an adequate written description of the broad genera of constructs or RNAs expressed from such that is commensurate with the breadth of what is now claimed, that will function to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean. It is noted here that the claim language in (a), "at least one target mRNA expressed in soybean, is not limited to genes that are encoded by the genome of soybean or "endogenous" to soybean but, as written, reads on any target mRNA expressed in soybean.

The specification as filed provides only a general disclosure of what is encompassed any target mRNA that can be expressed in soybean, the expression of which can be reduced by an RNA or the expression of an RNA having 80% homology to

all or part of said target mRNA or any endogenous gene the expression of which can be reduced by an RNA or the expression of an RNA having 80% homology to all or part of said endogenous mRNA. The specification provides general guidance and several examples of target mRNAs and endogenous mRNAs, the expression of which are reduced in soybean, but does not indicate or disclose any distinguishing identifying characteristics of these mRNAs that would indicate that applicant was in possession of the broadly claimed genera of constructs and RNAs commensurate with what is now claimed, that will function to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean.

However, the general guidance and examples provided by the specification are insufficient to indicate possession of the broadly claimed genera of constructs and RNAs as claimed. The specification does not provide the specific guidance that would be required to allow the skilled artisan to recognize that Applicant was in possession of the broad genera as claimed or of a representative number of species of broad genera of constructs and RNAs that functioned commensurate with what is now claimed: nucleic acid constructs and RNAs that comprise a sequence homologous to and that reduces the expression of any nucleotide sequence that is at least 80% homologous to all or part of any target mRNA (which can be any RNA from any source) which can be expressed in soybean or any endogenous mRNA expressed in soybean.

What is the structure of a construct or an RNA expressed from such, for example, that, when expressed in soybean, will function commensurate with what is now claimed, to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean so as to indicate that Applicant was in possession of what is now claimed?

MPEP § 2163[R-2] I. states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.
>
> The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.
>
> Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").
>
> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of what is now claimed. Applicant has not shown how the invention was "ready for patenting" such as by the disclosure of a representative number of species of constructs or RNA expressed from such that will function commensurate with the breadth of the genera of constructs, RNAs and methods as claimed or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genera as claimed.

12. Claims 53-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for constructs, RNAs expressed from such and methods of using constructs and RNAs expressed from such for reducing the expression of fad2, delta9, gas1 and gas2 in soybean, does not reasonably provide enablement for constructs, RNAs expressed from such and methods of using constructs and RNAs expressed from such to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

In the instant case, claims 53-59 are broadly drawn to subject matter that has not been adequately described in the specification such that one of skill in the art can neither determine the metes and bounds of what is now claimed nor clearly recognize that Applicant was in possession of the invention commensurate with what is now claimed (as outlined in previous rejections herein). Given the lack of definiteness in the claims and the lack of written description in the specification, although the level of ordinary skill in the art is acknowledged as quite high, one of skill would still require specific guidance to practice the claimed methods, with the resultant specified biological effect of gene inhibition, commensurate in scope with what is claimed. However, the specification does not provide the requisite guidance such that any person skilled in the art would be able to make the instantly claimed constructs or RNAs expressed from such or to practice the claimed methods commensurate with their full scope, without performing undue *de novo* trial and error experimentation. This experimentation would be required, at least, to identify and characterize the vast number of target mRNAs and endogenous mRNAs, the expression of which could be reduced in soybean by the

nucleic acid constructs, RNAs and methods of the invention that comprise and employ a sequence homologous to and that reduces the expression of any nucleotide sequence that is at least 80% homologous to all or part of any target mRNA (which can be any RNA from any source) which can be expressed in soybean or any endogenous mRNA expressed in soybean.

Thus, while the specification is enabling for the examples set forth in the disclosure, the specification is not enabling for the full scope of what is now claimed. One of skill in the art could not practice the invention commensurate in scope with the claims without undue, *de novo* trial and error experimentation. Additionally, the type of experimentation required to practice the invention more broadly than is exemplified is a factor in the enablement analysis, but is not dispositive. In this case, even if the nature of each experiment required to expand the scope of the enabled invention was considered standard (which it is not), it would be out weighed by the sheer quantity of experimentation required to practice the full scope of the claimed invention.

Response to Arguments

13. Applicant's arguments filed 10/21/05 have been fully considered but they are not persuasive for the reasons set forth below.

Applicant has argued that Example 10 of the specification as filed describes suppression of the GAS gene using constructs comprising ELVISLIVES and points to a particular plasmid construct that was introduced into plants and reduced the expression of raffinose sugars. Applicant then points to the Declaration of Dr. Johan Stoop under

37 CFR 1.132 filed 10/21/2005 (which is addressed fully below) which details a single example of the reduction of GAS3 using the claimed construct wherein GAS3 shares less than 80% sequence identity with GAS1 and GAS2 (pg. 7). Applicant argues that the above arguments and Declaration are equally apposite with respect to the outstanding enablement rejection. Applicants arguments are addressed fully in the response to the abovementioned Declaration set forth below.

14. The Declaration of Dr. Johan Stoop under 37 CFR 1.132 filed 10/21/2005 has been fully considered and is insufficient to overcome the rejection of instant claims 53-59 based upon 35 U.S.C. 112, first paragraph written description and scope of enablement, as set forth in the last Office action.

Applicant has presented arguments, in the remarks referred to in section 15 and in the above declaration, that are drawn to the suppression of GAS gene expression as set forth in Example 10 (pg. 2). Applicant's presents the description of the suppression of GAS1 and GAS2 gene expression as set forth in Example 10 and presents data with regard to the suppression of GAS1, 2 and 3 gene expression using the constructs of the invention that comprise sequences homologous to the GAS 1, 2 or 3 genes (pg. 2). Applicant then presents arguments with regard to the percent of nucleotide sequence identity shared between the GAS 1, 2 and 3 genes and draws that conclusion that, "One skilled in the art would inexorably conclude that since the sequence identity between the GASI and 2 fragments and the full length sequence of GAS3 is about 70% and the observed suppression of GAS3 was 39% as discussed in paragraph 4 above, then it

would be reasonable to expect that RNA sequences homologous to all or part of the target mRNA would function to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with RNA sequences homologous to all or part of the target mRNA" (pg. 3, #6).

However, Applicant's arguments are not persuasive because the disclosure of the specification and the arguments presented above remain drawn to a limited number of species of the invention, whereas the claims are not so limited and continue to read on extremely broad genera of constructs, RNAs and methods which are not adequately described. In the instant case, the specification as filed and the arguments presented above do not provide a disclosure of a representative number of species of constructs or RNA expressed from such that will function commensurate with the breadth of what is claimed, that will the expression of any nucleotide sequence that is at least 80% homologous to all or part of any target mRNA (which can be any RNA from any source) which can be expressed in soybean or any endogenous mRNA expressed in soybean or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genera as claimed.

Additionally, in regards to Applicant's arguments with regards to the outstanding rejection under 35 U.S.C. § 112 1st paragraph, scope of enablement, while the specification is enabling for the examples set forth in the disclosure, the specification is not enabling for the full scope of what is now claimed. One of skill in the art, in particular in light of the lack of written description and indefiniteness in the claims, could

not practice the invention commensurate in scope with the claims without undue, *de novo* trial and error experimentation.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 517-272-0811811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba

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